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23-gauge versus 25-gauge vitrectomy for proliferative diabetic retinopathy: A comparison of surgical outcomes

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Running Head

A comparison of small gauge vitorectomy for proliferative diabetic retinopathy

Key words

23 gauge

25 gauge

Vitrectomy

Proliferative diabetic retinopathy

Postoperative vitreous cavity haemorrhage

Diabetic vitrectomy

Abstract

Purpose: This study compared clinical outcomes and complications between 23-gauge (23g) and 25-gauge (25g) transconjunctival sutureless vitrectomy in patients with proliferative diabetic retinopathy.

Study design: This was a retrospective study using data prospectively defined and collected. 80 eyes underwent 23g transconjunctival sutureless vitrectomy, and 80 eyes underwent 25g surgery using the same vitrectomy system by one surgeon. Primary outcome measures were best-corrected visual acuity, intraocular pressure, and incidence of intraoperative and postoperative complications.

Results: Vision was significantly improved after intervention in both groups (p=>0.0001). There was no significant difference in visual outcomes between the groups (p=0.43) or in the type and frequency of retinal breaks occurring during surgery (p=0.63). The 23g group had significantly more patients with a day one IOP of less than 6mmHg (p=0.034) and significantly more requiring a sclerostomy suture postopertively (p=0.014).

Conclusion and Message: Both gauges are equally effective for the treatment of proliferative diabetic retinopathy.

Introduction

The first commercially available narrow gauge vitrectomy system was described by Fujii et al. in 2002 [1]. Due to their perceived advantages increasing numbers of vitreo-retinal surgeons are now employing narrow gauge systems. These advantages include faster postoperative recovery with less postoperative discomfort, reduced surgically induced astigmatism and a quicker entry and exit from the eye [2,3]. Shortly after the first 25-gauge (25g) system was launched, 23-gauge (23g) systems became popular. 23g was rapidly adopted as it retained the fluid dynamics and instrumental rigidity offered by the 20-gauge (20g) systems and required minimal change in surgical technique. Subsequently 25g systems have been revised to make the instruments more rigid and with improved fluidics, which has resulted in an increased uptake for 25g. The Practice and Trends (PAT) survey of the American Society of Retina Specialists found that the percentage of surgeons who prefer small gauge surgery continues to increase. Over 90% of the 2013 survey participants stated that they most often employed small-gauge vitrectomy systems (either 23g or 25g), 20g vitrectomy was most often used by 3.7% to 7.2% of participants [4].

The utility of narrow gauge vitrectomy, both 25g and 23g, for a wide range of procedures has been demonstrated [6,7,8]. Numerous studies have favourably compared aspects of narrow gauge surgery to traditional sutured 20g surgery [9,10,11]. Studies have also found a reduction in peripheral retinal break formation near the sclerostomy sites with the cannulated sclersotomies used in narrow gauge systems [12,13].

Surprisingly little investigation has been carried out into whether there are any differences in outcomes between 23g and 25g surgeries. Although commonly grouped together there are multiple differences between 23g and 25g systems including sclerostomy size, instrument stiffness and utility, as well as fluidic capabilities and tissue attraction [3,14]. A comparison of small gauge systems is now of particular relevance given that 27-gauge (27g) systems are becoming available[15].

This study focuses on a series of patients who were undergoing 23g and 25g vitrectomy for proliferative diabetic retinopathy (referred to as diabetic vitrectomy) by one surgeon over a three year period. In particular we analysed intraoperative and postoperative events to see if there were any differences in outcome between the two gauge sizes.

Methods

This is a retrospective, comparative, and consecutive record review conducted in the Sunderland Eye Infirmary. A consecutive series of patients who had undergone primary pars plana vitrectomy for the complications of proliferative diabetic retinopathy by one surgeon at Sunderland Eye Infirmary from January 2010 to March 2013 were prospectively identified, and data using predetermined definitions, entered onto the surgeons own electronic database. For analysis the cases were divided into two groups:

1) A group dating from January 2010 to September 2011 where only 23G vitrectomy surgery was carried out.

2) A second group from October 2011 to March 2013 where only 25G vitrectomy surgery was carried out.

A variety of pre, intra and postoperative characteristics for the patients were recorded, including age, sex, type and duration of diabetes. The amount of preoperative PRP administered was graded as equal to, or more than, ETDRS full scatter, less than standard ETDRS full scatter or no preoperative laser [16]. The extent and position of VR adhesion present was recorded as per Yorston et al into none, disc attachment only, posterior pole attachment only or 1-4 quadrants of anterior vitreo-retinal attachment [17]. Patients were followed up at 1 day, two weeks, and six months postoperatively as a minimum and as needed according to the clinical circumstances.

All surgeries were carried out using the Alcon Constellation 23 and 25g + systems (Alcon, Forth Worth, USA). A wide-angle non-contact indirect viewing system, with an in-built image inverter, was used in all cases. The Edge plus one step entry system was used in all cases and the technique was common to both gauges. After conjunctival displacement, acutely oblique entry into the sclera was made with the trochar and continued until the sclerostomy cannula abutted the sclera. The trochar was then moved to 30 degrees to the globe and final entry made.

Core vitrectomy was carried out using a cut rate of 5000 cuts per minutes (CPM) with proportional vacuum settings and a maximum vacuum of 350mmHg for 23g and 550mmHg for 25g. Intraocular pressure was set at 26mmHg with the IOP compensation system activated for both groups with intermittent raised pressure for haemostasis as required. After core vitrectomy, delamination and removal of all posterior hyaloid face and fibro-vascular membrane was carried out. This was carried out primarily with the vitreous cutter alone and intra-vitreal scissors only if necessary. When performing cutter delamination a 3D mode was used with a biased closed duty cycle, and a cut rate of 3000 CPM declining to 1500 CPM as previously described [18]. In no cases was a sclerotomy opened up for 20 gauge instruments. Careful inspection to detect the presence of vitreo-schisis was made and staining of residual vitreous gel using diluted triamcinolone was used routinely in all cases. Any vitreoschisis detected was peeled using the vitreous cutter and forceps as necessary. Peripheral vitreous was removed, especially around the inner sclerotomy wounds, with deep scleral indentation.

Endolaser retinal laser photocoagulation was carried out to complete any deficiencies in previous laser and was also carried out up to the ora serrata in all eyes. An internal search using endo-viewing and indentation with a non-contact wide field viewing system was performed. Retinal breaks were treated with argon laser retinopexy or cryotherapy. Breaks were classified as being either posterior and usually related to dissection or surgical traction or peripheral related to vitreous separation- these were further divided into entry site related occurring with one clock hour either side of the sclerostomies or other vitreous separation related breaks. Silicone oil, Sulfur hexafluoride (SF_6) gas or air were used as postoperative tamponade where needed. Preoperative anti VEGF therapy was used in selected patients relating to the activity and extent of the neovasculariation. Combined phacovitrectomy was carried out in cases with visually significant cataract obscuring the operative view.

At the end of surgery, and after sclerostomy guard removal sclerostomy closure was checked by inflating the eye to a pressure of 30mmHg using a 30g needle inserted through the pars plana connected to an airline. If any sclerostomy leak was present an 8/0 absorbable suture was used to secure the wound.

Postoperative vitreous cavity clarity was recorded on a 4 point scale from 0-3 with 0 being completely clear to 3 being a dense haemorrhage with no red reflex visible as used previously [19]. Any postoperative vitreous cavity haemorrhage was categorised as early (present on first postoperative day or occurring within the first postoperative 3 week period) or late (occurring greater than 3 weeks postoperatively).

Eyes with previous vitrectomy surgery were excluded from the study. One patient in the 23g group and two in the 25g group had silicone oil used and these were excluded from further analysis but are presented in Table 5.

The groups were compared using Minitab 16 (Minitab Ltd, Coventry, UK) for statistical analysis. Case characteristics were calculated using descriptive statistics, including mean and SD. Categorical variables were compared using Fisher's exact test and Pearson's χ^2-test as appropriate. Means were compared using Student's *t*-test for unequal variance. *P*-values of <0.05 were considered statistically significant. Snellen chart measurements were converted to logarithmic minimum angle of resolution, LogMAR, for statistical analysis. Acuity values were assigned to counting fingers and hand motion as recommended by Holladay [20].

Results

During the study period there were 80 eyes of 78 patients who had 23 gauge vitrectomy and 80 eyes of 79 patents that had 25 gauge vitrectomy for complications related to proliferative diabetic retinopathy. Eyes with previous vitrectomy surgery were excluded (0) as were eyes which required silicone oil (3).

The groups were well matched with a mean age of approximately 52 years old. In particular the duration of diabetes, HbA1c and the use of blood thinning agents preoperatively did not differ significantly. The groups were also similar in terms of their indications for surgery and complexity in terms of the extent of vitreoretinal attachment present (Table 1).

Six month follow up was achieved in 96% and 97% of the 23g and 25g groups respectively. Both groups had significantly improved vision at 6 months (p=>0.0001) but there were no significant differences between visual acuities at any of the time points recorded (Table 2).Similarly the frequency of cataract surgery following vitrectomy was equivalent.

Eighteen (23%) eyes in the 23g group required at least one sclerostomy suture compared to only 6 (8%) eyes in the 25g group. (p=0.014). There was no significant difference between mean day 1 and day 14 IOPs but there were significantly more patients with a day one IOP of less than 6mmHg in the 23g group(p=0.034) (Table 2).

Scissors were necessary in 6 patients in the 23g group and 3 patients in the 25g group (p=0.49). There was no significant difference in the type and frequency of retinal breaks between the two groups (Table3). There was one case of postoperative retinal detachment in the 23g group and none in the 25g group (Table 3).

There were no significant differences between the day 1 and day 14 vitreous cavity clarity secondary to haemorrhage between the groups or rate of occurrence of early and late postoperative vitreous cavity haemorrhage (Table 2).

Table 4 details adverse outcomes which were encountered during the study and Table 5 discusses the excluded eyes which required silicon oil.

Discussion

This study sought to compare surgical outcomes for 25g and 23g vitrectomy surgery for diabetic vitrectomy. We choose diabetic vitrectomy because of the well-known side effect and complication profile. The 160 surgeries analysed were carried out over a three year period by a single surgeon. Our 23g and 25g cohorts were both well matched, with none of baseline variables recorded differing significantly between the groups. Importantly the surgical complexity was well matched with no significant difference in the extent of vitreoretinal adhesion between the two groups.

Visual improvement and rates of surgical complications were broadly similar between the groups. The only outcomes which reached significance were the increased frequency of sclerostomy suture and postoperative hypotony in the 23g.The two groups used the same entry system design and oblique entry technique and the difference must relate to the size of the sclerostomy. At the conclusion of surgery all eyes, even if not requiring tamponade had a partial fluid air exchange and then had the eye inflated to a pressure of 30mmHg with a 30g needle. More 23g sclerostomies required suturing based on this protocol. Despite this there was still a higher hypotony rate in the 23g group on the first day. Transient hypotony (IOP <6) one day postoperatively occurred in 10% of 23G and 2% of 25g surgeries in out cohort, this was a significant difference (p=0.034). Transient hypotony of 23g has been noted by several other studies. Park et al, found 0% (66/101) of their 20g and 22% (45/101) of their 23g group to be under <8mmhg, at day 1 postoperatively [21]. Both Akçay al. and Lotte et al similarly found high rates of transient hypotony in 23G studies; 9.8% (34/350) and 10% (10/100) of eyes treated with 23g had 1 day post op IOP of <6 [22,23].

It is well recognised that 20 gauge surgery carries less risk of day one hypotony. Framme et al studied IOP post 20g surgery and found that transient low IOP was infrequent at 1.2% (10/851) eyes (24). IOP post 25g surgery has been less frequently investigated, Gupta et al. found a rate similar to our study of 5.7% (4/75) [25].

A feared consequence of day 1 hypotony is intraocular haemorrhage and with the larger sclerostomies. Therefore we may have expected to have found an increased incidence of day 1 vitreous cavity haemorrhage in the 23g on account of the higher rate of day 1 hypotony in this group. This however was not found; both groups had similar rates of POVCH both early and late. This could be due to the sample size being too small to detect any difference.

Previous studies into small gauge surgery for diabetic vitrectomy have compared rates of POVCH between 20g and 23g systems, or evaluated a specific gauge independently. POVCH has been reported as being more frequent with larger gauge instruments. Yang et al recorded a one month re-bleed rate of 18% in 20g and 7% in 25g [26]. Farnouk et al reported a rate of 11% series of 200 25g operations [27]. Our study did not find there to be any marked difference in re-bleed rates between 23g and 25g at any time period. The total number of patients requiring further surgery for POVCH was 9% in the 23g group and 6% in the 25g group (p=0.77). These results are similar to the 10.4% reoperation rate found by Schoenberger et al. in series of 174 25g operations [28].

A reported benefit of transconjunctival small gauge surgery over 20g is faster visual recovery [12,13]. This study did not find that this trend continues when comparing 23g to 25g. We found no significant difference in the speed of visual recovery between the groups using the 14 day and 6 month time points as a guide.

The settings used for core vitrectomy between the two gauges actually result in very similar achievable flow rates in vitreous and we did not note any clinically relevant difference in the duration of surgery between the groups although did not record this systematically. However as gauge size reduces the sphere of influence of fluid flow around the port reduces [14]. The effect of the vitrectomy probe induced fluid flow is therefore more localised in smaller gauges meaning that it exert less traction on distant tissue and with the smaller port size is more exact when carrying out cutter dissection. This may mean that scissor use will less often be required and that the iatrogenic break rate may reduce with smaller gauge. We did not find this however between 23g and 25g. Several papers have reported that significantly fewer peripheral retinal breaks are caused by cannulated 23g systems compared to the 20g [12,13,29]'. Our entry site break rate was very low in both groups at 1 eye in each group as may have been expected as the cannulated sclerostomy system is identical in length in each gauge at 6mm.The use of scissors was marginally greater in the 23g group and there was a non-significant higher number of posterior iatrogenic breaks and other posterior vitreous detachment related breaks and it may be that larger studies would show a difference. It will be of great interest to contrast our reported rates of peripheral retinal breaks and other complications with the upcoming 27g system to see if any significant advantage can be accrued by having a yet smaller gauge system. There was only one cases of postoperative detachment in the study and underlies the importance of break detection and treatment for detachment prevention.

There has been a long running debate over a possible higher rate of endophthalmitis in transconjunctival narrow gauge surgery compared to sutured 20g surgery. Earlier research found that rates were increased in smaller gauge surgery [30]. However more recent and larger studies have found no significant difference in the rate of endophthalmitis with smaller gauge surgery [31,32]. It is likely that these differing conclusions reflect the evolution of small gauge surgery; improving surgical technique and advancing technology have perhaps resulted in a falling incidence of endophthalmitis. We had no cases of endophthalmitis in either group but the incidence of this complication is very low and substantially larger studies would be needed to investigate this further.

This study has several strengths. It is the largest direct comparison between of 23g and 25g surgical outcomes for diabetic vitrectomy, with all operations were carried out by a single surgeon. Every new surgical system has a learning curve but the surgeon had been using both 23g and 25g surgery for several years before the data was gathered. Both groups in the study were well matched medically and demographically. Lastly its findings are in keeping with previous works which looked at 25g and 23g gauge systems in isolation.

It does however also have several weaknesses. Firstly, as with many vitreoretinal studies there is insufficient power to facilitate comment on rarer outcomes such as rates of endophthalmitis. Secondly, due to the retrospective, chronological nature of the study patients could not randomised between groups. Lastly, it could be argued that as the surgeon progressed to using the 25g instruments his operative skill would have also progressed, however he had already been using 25g for 5 years for other conditions so this effect was unlikely to be significant. It is possible however that a surgeon unfamiliar with 25g may have achieved different results. It is also possible that with an alternative surgical system, different results between the gauges may have been found.

The fundamental finding of this investigation is that both 23g and 25g systems are highly effective for treating proliferative diabetic retinopathy. Advocates of the individual gauges have argued the advantages of both with the perceived advantages of 23g over 25g being its similar instrument handling to 20g and the advantages of 25g being its fluidic behaviour and smaller sclerostomy size. Our study shows that both can achieve good visual outcomes with a similar and low rate of post-operative complications. Our study did however indicate that operations conducted with the 25g system were less likely to induce transient hypotony or require a sclerostomy suture.

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